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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,263	10/31/2000	Anthony J. Cutie	540541-2013.1	1107

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NEW YORK, NY 10151

EXAMINER

DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
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DATE MAILED: 05/06/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/702,263

Applicant(s)

CUTIE ET AL.

Examiner

Jose' G. Dees

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9, 16 and 17 is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Claims 1-17 are pending in this application. Acknowledgement is made of Applicant's Terminal Disclaimer filed 1/6/03.

Claims 1-9, 16 and 17 are allowed.

Applicant's arguments filed January 6, 2003 and October 21, 2002 have been fully considered but they are not persuasive. The delay in making the following rejection is regretted.

Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rieveley (6,153,632) in view of Whitcomb (6,011,049) and Byrd (6,197,340).

Rieveley teaches the treatment of diabetes mellitus by combining an insulin sensitizer with the insulin, thereby enabling cells of the body to function with lower levels of insulin (col. 5, lines 52-67). A list of suitable insulin sensitizers include pioglitazone HCl. The insulin can be biguanide, such as metformin or glucophage.

Whitcomb teaches the use of pioglitazone plus metformin together in a single formulation, such as a tablet or capsule (col. 4, lines 31-37). These combinations produce better than expected control of non-insulin dependent diabetes mellitus (col. 5, lines 2-6).

Byrd teaches an oral formulation comprising a combination of ingredients. Col. 6, lines 60-67 teach guanids include compounds such as metformin, phenformin and buformin.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to produce a formulation comprising a combination of pioglitazone HCl and metformin, phenformin or buformin to treat diabetes mellitus. The prior art clearly teach drug combinations to allow attachment of insulin to insulin-insensitive cells (col. 5, lines 56-67 of Rieveley).

Applicant argues that Rieveley amounts to picking and choosing to arrive at the claimed combination and Whitcomb does not per se reveal pioglitazone HCl and metformin.

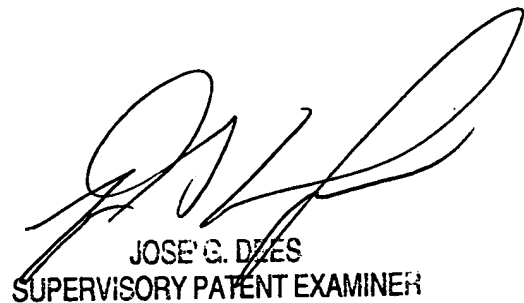
It is the examiner's position that the combination of references renders the claimed invention obvious. Clearly column 5, lines 2-6 of Whitcomb teach pioglitazone HCl and metformin. Further, Rieveley and Byrd teach that the biguanides are equivalent to make other combinations.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jose' G. Dees whose telephone number is 703-308-4628. The examiner can normally be reached from 9:30 to 6:00. •

The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



JOSE G. DEES
SUPERVISORY PATENT EXAMINER

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